Remarks

A two month extension of time is submitted herewith.

Examiner has rejected the figures due to typographical errors and the terms "HEMA" and "CYST" as being unclear as to what chemicals they represent. Applicant submits herewith new figures in compliance with 37 CFR 1.121(d). In each Figure, HEMA has been replaced with 2- Neely et al. (10/748,621), hydroxyethyl methacrylate and CYST has been replaced with cystamine. Support for this amendment may be found in the original description of the Figures, page 2, lines 18-29.

Examiner has objected to the use of the word "said" in the abstract. Applicants have replaced the word "said" with the word "the". Applicants respectfully submit that the objections to the Figures and abstract have been traversed.

Claims 1-22 and 24-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lai (US 5,451,651) in view of Nochumson (US 4,542,200), Monestere (US 4,923,480), and Rudnick (US 2,321,046).

The present invention relates to

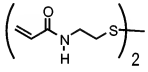
> a process for making an antimicrobial lens having consistent quantities of silver bound thereto. Specifically, the process of the present invention comprises curing a monomer mixture comprising lens forming components and at least one ligand monomer under conditions sufficient to provide a relative reactivity ratio of the ligand monomer to a major lens forming component of at least about 0.45 and contacting said lens with a silver containing solution to form an antimicrobial lens comprising silver ions in an amount greater than about 80% of a target silver concentration. Page 3, lines 2-9.

The present specification goes on to say

> It has been found that by controlling the polymerization or cure conditions uptake of silver may be greatly improved. Polymerization conditions sufficient to provide a ligand monomer to lens forming component reactivity ratio of greater than about 0.45 and preferably greater than about 0.5 form a lens which

> is capable of taking up at least 80% of a target silver concentration and preferably greater than about 85% of the target silver concentration, and in some embodiments more preferably greater than about 90% of the target silver concentration. Present specification, page 23, lines 24-31.

Claim 1 recites a method comprising curing under conditions sufficient to provide a specific reactivity ratio, a monomer mix comprising at least one lens forming monomer, and at least one ligand monomer to form a lens. The lens is treated with a silver solution "to form an antimicrobial lens comprising silver in an amount which is at least about 80% of target silver concentration". In the current election, Applicants elected ligand monomers of the formula



and lens forming components which would form senofilcon A lenses.

Lai et al. discloses "urea and urethane-containing monomers for contact lens materials". Abstract. None of the urea or urethane-containing monomers disclosed in Lai et al. include sulfur, as is required in the elected ligand monomer. Lai et al. also does not disclose silver, or contact lenses made from senofilcon A.

Nochumson discloses "electrophoresis medium, comprising a copolymer of acrylamide and an ethylenically unsaturated resin formed by replacing at least some of the hydroxyl hydrogens in a polysaccharide with an ethylenically unsaturated group". Abstract. Nochumson discloses that N,N'-bisacrylylcystamine can be used as a crosslinker. Nochumson does not disclose contact lenses, senofilcon A polymers, that the N,N'-bisacrylylcystamine could be used for any purpose other than as a crosslinker or that silver be included in a contact lens.

Monestere discloses a process for opaquing and tinting a contact lens by depositing an opaquing medium "on the lens anterior surface as discrete randomly sized, randomly positioned droplets from a fine mist spray". Abstract. Monestere further discloses that the mist can be a silver nitrate solution, that the drops are allowed to remain in place on the surface for a sufficient time to penetrate the lens, and that the lens is then "immersed in a precipitating agent, e.g., a sodium chloride solution, where it is allowed to remain for at least about one minute during which time the sodium chloride reacts with the silver nitrate to precipitate silver chloride. When the silver chloride precipitate is thereafter exposed to light, metallic silver as the actual opaquing material will be released in the lens." Column 2, lines 56-63. Monestere does not disclose including any ligand monomer in the contact lens formulation, and does not suggest that silver could be associated with the lens by any means other than precipitation. Monestere also fails to disclose or suggest that when a ligand monomer is used, it is important to control the reactivity ratio of the ligand monomer to the lens forming components.

Rudnick et al. "relates to the preparation of photo-mechanical negatives to be used for the photo-mechanical reproduction of drawing sheets, mechanical layouts, templates, etc." Column 1, lines 1-4. Examiner has relied upon Rudnick et al. to show that silver nitrate is photosensitive. Photosensitivity is not an element of the present claims. Rudnick et al. does not disclose or suggest any element of the present claims.

The only method of incorporating silver suggested by any of the cited references is precipitating silver metal, as disclosed in Monestere.

There is nothing in Lai et al., Monestere or Nochumson which would suggest that any monomer could be incorporated into a lens formulation and used as a ligand monomer to reversibly bind silver. None of the references disclose an antimicrobial lens. Nor is there any suggestion to cure a reaction mixture containing the ligand monomer under reaction conditions "sufficient to provide a reactivity ratio of the ligand monomer to at least one major lens forming component of at least about 0.45 lens" as is recited in the present claims.

Assuming a prima facie case of obviousness had been made, the present application contains a showing of surprising results sufficient to rebut same.

Examples 4-10 clearly show that at reaction conditions which do not provide the recited reactivity ratio (Examples 8-10) the desired amounts of silver are not incorporated. The cited references are completely silent with respect to this effect.

Applicants respectfully submit that the rejection based upon the combination of Lai et al, Nochumson and Monestere has been traversed.

Claims 1-44 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1044 of copending Application Meyers et al. (10/703,770). Meyers et al. has been abandoned in favor of the present application.

Claims 1, 7-8, 13, 15, 19, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 of copending Application Neely et al. (10/183,883). Neely et al. disclose "a method of producing an antimicrobial lens ***without an antimicrobial host*** comprising placing a lens in an antimicrobial containing solution." Claim 1, Neely et al. Ligands are specifically listed as an antimicrobial host. Page 3, line 22. Accordingly, Neely et

al. specifically excludes the inclusion of a ligand monomer in the lens polymer. Applicants respectfully submit the present claims are patentable over Neely et al.

Claims 1, 7-8, 13, 15, 19, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9 and 23-24 of copending Application Rathore et al. (10/715,745), claims 1, 10-11, and 17 of copending Application Andersson et al. (10/719,903), claims 1-3, 9-12, and 18 of copending Application Neely et al. (10/748,621), and claims 1 and 7-10 of copending Application Nayiby et al. (10/882,072).

Rathore et al. does contact lenses comprising at least one ligand monomer and silver. However, Rathore et al. does not disclose or suggest cure conditions which provide the reactivity ratios recited in the present application. Specifically, Rahtore et al. is silent as to the cure intensity which is used. As shown by the Examples of the present application (and particularly Example 11), cure intensity is an important factor in achieving the recited reactivity ratio.

Andersson et al. discloses ophthalmic lenses comprising antimicrobial metal salts. Ophthalmic lenses comprising ligand monomers which reversibly bind silver, and processes which use reactivity ratios necessary to achieve the desired silver loading are not disclosed or suggested.

Neely et al. discloses contact lenses comprising a ligand monomer and silver in a specified silver to ligand ratio. To expedite prosecution a terminal disclaimer over Neely et al. is filed herewith.

Nayiby et al. discloses solutions for packaging ophthalmic devices comprising at lest one antimicrobial metal ***salt***. Abstract, emphasis added. Nayiby et al. discloses

neither contact lens formulations comprising at least one ligand monomer, nor the curing conditions necessary to provide the recited reactivity ratios.

Applicants respectfully submit that Examiners rejections based upon Neely et al., Rathore et al., Andersson et al., Neely et al. and Nayiby et al. have been traversed.

Withdrawal of the rejections and allowance of the claims is respectfully requested.

Respectfully submitted,

By:____/Karen A. Harding/
Karen A. Harding
Reg. No. 33,967

Johnson & Johnson
One Johnson & Johnson
New Brunswick, NJ 08933
(904) 443-3074
Dated: May 30, 2008